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Human Factors Analysis of the CardioQuick Patch ®: A Novel Engineering Solution to the Problem of Electrode Misplacement during 12-lead Electrocardiogram Acquisition

Raymond R. Bond¹, Dewar D. Finlay¹, James McLaughlin¹, Daniel Guldenring¹, Andrew Cairns¹, Alan Kennedy¹, Robert Deans², Albert L. Waldo³, Aaron Peace⁴

¹Ulster University, Jordanstown campus, Shore Road, Newtownabbey, Co. Antrim, BT37 0QB, Northern Ireland, UK

²eNNOVEA Medical, 2030 Dividend Drive, Columbus, Ohio 43228, United States

³Harrington Heart & Vascular Institute, University Hospitals Case Medical Center, Division of Cardiovascular Medicine, 1100 Euclid Avenue, Cleveland, OH 44106

⁴Altnagelvin Hospital, Department of Cardiology, Western Health and Social Care Trust, Glenshane Road, BT47 6SB, Londonderry, Northern Ireland, UK

Introduction: The CardioQuick Patch ® (CQP) has been developed to assist operators in accurately positioning precordial electrodes during 12-lead electrocardiogram (ECG) acquisition. This study describes the CQP design and assesses the device in comparison to conventional electrode application.

Methods: 20 ECG technicians were recruited and a total of 60 ECG acquisitions were performed on the same patient model over four phases: (1) all participants applied single electrodes to the patient; (2) all participants were then re-trained on electrode placement and on how to use the CQP; (3) participants were randomly divided into two groups, the standard group applied single electrodes and the CQP group used the CQP; (4) after a one day interval, the same participants returned to carry out the same procedure on the same patient (measuring intra-practitioner variability). Accuracy was measured with reference to pre-marked correct locations using ultra violet ink. NASA-TLK was used to measure cognitive workload and the Systematic Usability Scale (SUS) was used to quantify the usability of the CQP.

Results: There was a large difference between the minimum time taken to complete each approach (CQP=38.58s vs. 65.96s). The standard group exhibited significant levels of electrode placement error (V1=25.35mm±29.33, V2=18.1mm±24.49, V3=38.65mm±15.57, V4=37.73mm±12.14, V5=35.75mm±15.61, V6=44.15mm±14.32). The CQP group had statistically greater accuracy when placing five of the six electrodes (V1=6.68mm±8.53 [$p<0.001$], V2=8.8mm±9.64 [$p=0.122$], V3=6.83mm±8.99 [$p<0.001$], V4=14.90mm±11.76 [$p<0.001$], V5=8.63mm±10.70 [$p<0.001$], V6=18.13mm±14.37 [$p<0.001$]). There was less intra-practitioner variability when using the CQP on the same patient model. NASA TLX revealed that the CQP did increase the cognitive workload (CQP Group=16.51%±8.11 vs. 12.22%±8.07 [$p=0.251$]). The CQP also achieved a high SUS score of 91±7.28.

Conclusion: The CQP significantly improved the reproducibility and accuracy of placing precordial electrodes V1, V3-V6 with little additional cognitive effort, and with a high degree of usability.

Introduction

The 12-lead Electrocardiogram (ECG) is an inexpensive tool that remains one of the most widely used diagnostic instruments in medicine, especially for assessing cardiac rhythm and function [1]. Whilst patient safety and intragenic errors are emerging concerns in medicine [2], the recording of the 12-lead ECG has also been subject to human error. Both limb electrodes and precordial electrodes are frequently misplaced or incorrectly interchanged. According to Bupp et al. [3], electrode misplacement can occur between 40% and 60% of the time. Wenger et al. [4] also found that 36% of precordial electrodes are misplaced outside a radius of 1.25 inches from the proper anatomical landmarks. In a review, Khunti et al. [5] stated that less than 20% of cardiologists and 50% of nurses correctly position electrodes V1 and V2.

Researchers have also studied the effects of electrode misplacement on the actual signals. When studying a common electrode misplacement problem (electrodes V1 and V2 are misplaced in the second intercostal space and the remaining electrodes are mostly inferiorly placed), Bond et al. [6] found that chest leads V2, V4 and V1 (in that order) are the most affected leads. Another similar study by Kania et al. [7] was in partial agreement and found that leads V2, V3 and V1 are the most affected leads. More importantly, researchers have shown that electrode misplacement can affect the clinician's interpretation of the ECG. It has been reported that electrode placement errors can mimic septal myocardial infarction [5]. It was also shown that superiorly misplaced electrodes V1 and V2 could normalise ST elevation and conceal an anterior STEMI [6]. Finlay et al. [8] have also shown how the effects of electrode placement can alter the sensitivity of an automated STEMI algorithm by up to 10%. Research studies have gone so far as to demonstrate how the electrode misplacement of limited lead systems alter the ECG signals and particularly the ST segment [9, 10]. Therefore electrode misplacement can conceal abnormalities or indeed result in a misdiagnosis, which in turn can lead to ineffective use of medical resources, inappropriate therapy or the withholding of timely treatment. At best, electrode misplacement would result in a second ECG recording. However, this also can delay medical intervention whilst increasing the likelihood of morbidity and

mortality in acute cases. Other consequences of improper electrode placement include the lack of reliable comparisons between previous and subsequent ECGs and the unreliability of using P wave morphology to help localize the location of supraventricular tachycardia.

The reasons for the prevalence of electrode misplacement are largely unknown, however it is well engraved into clinical practice. For example, a study found that Internet images that would be returned after a search for illustrations of 'ECG electrode positions' are very poor in terms of accuracy and utility [11]. Therefore, instructors or clinicians who use online images as a reference for clinical practice are likely being misled by these references.

Potential solutions to the electrode misplacement problem have been developed over many decades. This has included, 1) algorithms to automatically detect electrode misplacement [12], 2) mnemonics to remind personnel to check for electrode misplacement [13], 3) educational tools and simulators to demonstrate the effects of misplacement [14-16] [17] and 4) human factored engineering solutions [18, 19]. Whilst computer algorithms would be ideal to detect such errors, not all ECG machines integrate these algorithms and they are not always sensitive to precordial electrode misplacement [20]. This is perhaps due to the fact that the algorithms only rely on a small number of features (i.e. rSr' in lead V1 and the lack of R wave progression), which in themselves can have confounders such as myocardial infarction, Brugada syndrome and dextrocardia [7]. Whilst mnemonics and simulators are useful, ECG textbooks do not detail the effects of electrode misplacement. And whilst there have been a number of engineering solutions such as electrode belts [19, 21], they have not been widely adopted, perhaps due to their expense, a lack of adaptability (the difficulty of 'one size fits all') and insufficient evidence of their efficacy. The work presented in this paper consists of an evaluation of a new engineering solution called CardioQuick Patch® (CQP), which was developed by eNNOVEA Medical (Columbus, Ohio, USA). Due to its unique design, the CQP is adaptable to all adult patients regardless of gender or torso size. This research looks to assess the CQP in comparison to standard single electrodes. Specifically, we aimed to discover if

the CQP does improve the accuracy of electrode placement. We also ascertain if the CQP improves the reproducibility of an ECG for serial comparison and whether the CQP can be applied in a time that is comparable to single electrode application. We also measure any additional cognitive load required by the operator to use the CQP, and, in addition we assess the usability of the CQP using a validated instrument.

Methods

The CQP (Figure 1) has been developed to assist operators in accurately positioning precordial electrodes by providing visual aids such as a reference for each electrode and anatomical lines to guide proper electrode application. The CQP is also disposable since it is manufactured using relatively inexpensive materials. The CQP can be applied to both males and females of all torso sizes. Whilst the horizontal placement of the electrodes are adaptable, the vertical placement is rigid. This is due to the fact that the CQP and its static vertical placement of the electrodes was standardised as a result of analysing intercostal spaces of >1000 cadavers. Whilst this means that the CQP may have a potential limitation, we hypothesize that it will improve upon the performance of using standard single electrodes. A unique feature of the CQP is the facilitation to document the exact electrode positions using the ruler markings that are displayed on the electrode strip itself. The CQP was also designed to stay on the patient for up to three days, which limits the intra-patient variability of applying multiple ECG electrode sets over a short space of time.

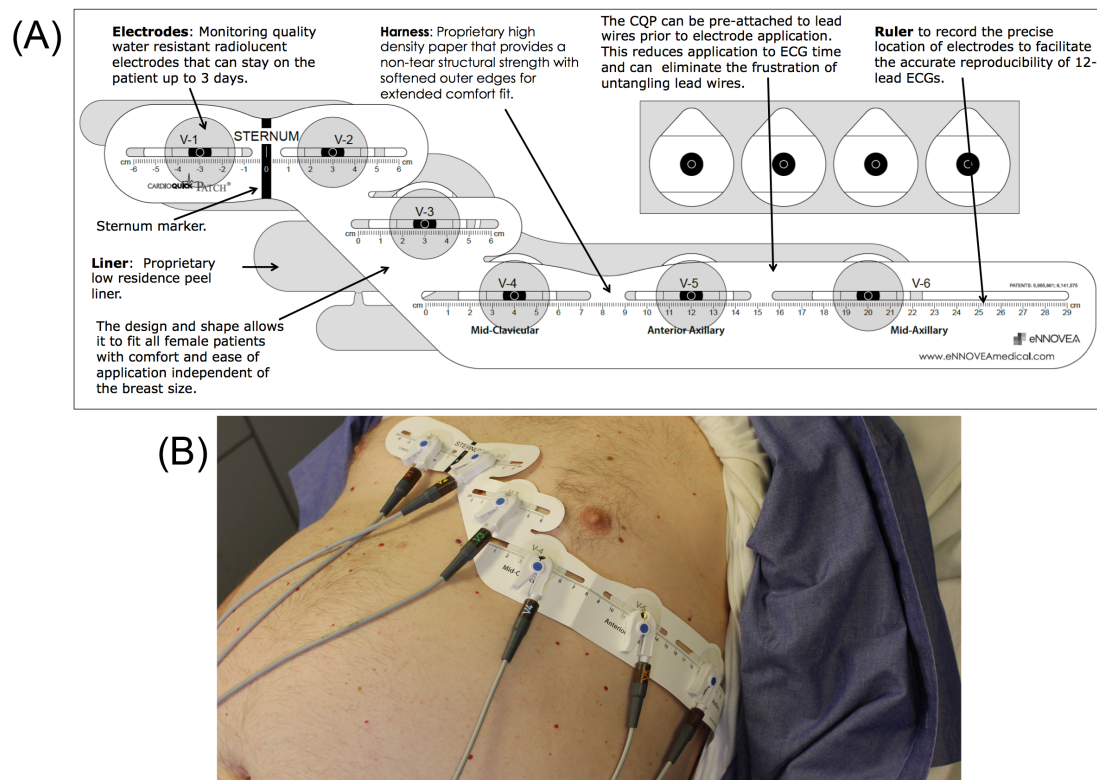


Figure 1. (A) Schematic of the CardioQuick Patch® or CQP developed by eNNOVEA Medical, (B) example of the CQP in clinical practice.

Study Design

Twenty operators (ECG technicians) were recruited, and a total of 60 procedures of ECG acquisition were performed on the same patient model (live **male** human: height=5ft 6", weight=230lbs) over four phases. These phases have been described in Table 1. Demographics for the participants were also collected (12 females, 8 males, mean age = 33.40 ± 10.77 , mean years of experience = 7.47 ± 6.77 , mean number of ECGs recorded per month = 47 ± 27.07).

Table 1. Description of each of the phases in the study design.

	Description
Phase 1	All 20 participants applied standard single TAB electrodes onto the patient model without any retraining.
Phase 2	All 20 participants were then re-trained on proper electrode placement, and on how to use the CQP. The training lasted 15 minutes and involved a demonstration of correct electrode application on a manikin.
Phase 3	Participants were randomly divided into two groups of 10 participants each. The standard group applied standard single TAB electrodes to the patient model whereas the CQP group applied the CQP to the patient model.
Phase 4	After a 24-hour period, both groups returned to carry out the same procedure on the same patient model. This was used to measure the reproducibility of the CQP in comparison to standard single electrode application.

Accuracy of electrode placement was measured with reference to the correct locations as predetermined by a consensus of two experienced practitioners who used the universal standard and pre-marked the correct positions onto the patient using invisible ultra-violet ink (V1=right of the sternum border at the 4th intercostal space, V2=left of the sternum border at the 4th intercostal space, V3=between V2 and V4, V4=midclavicular line on the 5th intercostal space, V5=same horizontal line as V4 on the anterior axillary line and V6=same horizontal line as V4 and V5 on the midaxillary line). After each participant applied the electrodes and left the room, the investigator measured the distance between the participant's applied electrode positions and the correct positions that were pre-marked. Distance was recorded in millimetres (mm) and the direction of misplacement was recorded using a common anatomical vocabulary,

i.e. Right Lateral [RL], Left Lateral [LL], Superior [S], Superior Right Lateral [SRL], Superior Left Lateral [SLL], Right Lateral [RL], Left Lateral [LL], Inferior [I], Inferior Right Lateral [IRL] and Inferior Left Lateral [ILL].

Given that the same groups returned to apply the same method of electrode application to the same patient model, we also measured consistency or the reproducibility of applying electrodes to the same patient. This was facilitated by the fact that we recorded both distance and direction, which allowed the authors to calculate the Euclidean distance between the first electrode application and the second electrode application by each participant. However, the Euclidean distance was approximated since only anatomical direction was recorded. However to measure ‘reproducibility’ we converted the anatomical directions to angles in degrees (where SRL=-120°, SLL=-60°, IRL=120°, ILL=60°, RL=180°, LL=0°, S=-90°, I=90°). Equation 1 details the metric we used to measure reproducibility.

Equation 1.

$$\text{ReproducibilityMetric} = \frac{1}{n} \sum_{i=1}^n \sqrt{(|dist_{1,i}| \cos angle_{1,i} - |dist_{2,i}| \cos angle_{2,i})^2 + (|dist_{1,i}| \sin angle_{1,i} - |dist_{2,i}| \sin angle_{2,i})^2}$$

Where n is the number of ECG technicians in a given group, $|dist_{1,i}|$ and $angle_{1,i}$ are the absolute distance and approximated direction in degrees of a given single electrode position during the first application (Phase 3) and $|dist_{2,i}|$ and $angle_{2,i}$ are the distance and direction of a given single electrode position of the second application (documented in Phase 4). The metric returns the distanced in *mm* between the first electrode position and the second electrode position, which can be used to show the intra-practitioner variability of electrode placement on the same patient.

Duration (i.e. time to complete the electrode application task) of both groups was also recorded. The NASA Task-Load Index (NASA-TLX) was used to measure the cognitive effort of both groups. The NASA-TLX is a widely used self-reported mechanism in the human-machine interaction community that is used to

measure the cognitive-workload of users [22]. Also, the validated Systematic Usability Scale (SUS) instrument was also used to quantify the usability of the CQP. SUS is also a widely used survey to measure the usability of user-machine interfaces [23]. It consists of 10 standard questions that have a 5-point Likert scale. Five questions (evenly numbered questions 2,4,6,8,10) consist of negative connotations (where 1 is ideal), and five questions (odd numbered questions: 1,3,5,7,9) have positive connotations (where 5 is ideal). Answers to the SUS survey are transformed into a usability score out of 100. The mean SUS score is calculated using Equation 2. This SUS score is then benchmarked against a known distribution (where mean=68 ± 20) of SUS scores.

Equation 2.

$$\overline{SUS} = \frac{1}{n} \sum_{i=1}^n norm \cdot \sum_{j=1}^m \begin{cases} q_{i,j} - 1, & q_{i,j} \bmod 2 > 0 \\ 5 - q_{i,j}, & \text{otherwise.} \end{cases}$$

where n is the number of participants ($n=10$) and m is the number of questions ($m=10$). Hence, $q_{i,j}$ is a rating given by one participant for one question. Ratings provided from odd numbered questions are subtracted by 1 and ratings from evenly numbered questions are subtracted from 5. The *norm* coefficient ($=2.5$) is used to normalize the SUS score to provide a number out of 100.

Statistical Analysis

Mean ± standard deviation (SD) of the accuracy of electrode placement in mm were calculated. Wilcoxon and Mann Whitney significance testing was used to compare performances between the two groups and within the groups where appropriate (where $\alpha=0.05$). All analysis was performed using the R programming language and the R Studio integrated development environment.

Results

Figure 2 shows the duration of electrode application when using standard single electrodes and the CQP. Whilst the CQP on average took less time to use, the

duration of using both approaches had no statistical significance (CQP group=84.06s±29.35 vs. standard group=89.07s±14.55, $p=0.50$). However, there was a large difference between the fastest times recorded for using both approaches (CQP=38.58s vs. standard electrodes=65.96s). In addition, the fastest CQP application was also very accurate where positions for electrodes V1, V2 and V3 were exact (other electrodes were slightly misplaced: V4=30, V5=20, V6=30.5). In comparison, the fastest standard electrode application had greater misplacement errors (V1=110, V2=70.5, V3=50, V4=30, V5=20.5, V6=50).

Figure 3. shows the distances between the correct electrode position and the participant's applied electrode position. Before the retraining event (Phase 1), the mean electrode misplacement for all participants was: V1=24.05mm±20.33, V2=19.05mm±18.70, V3=38.85mm±24.52, V4=32.05mm±17.62, V5=28.55mm±18.15, V6=32.39mm±21.84. After the retraining event, the standard electrode group exhibited similar levels of misplacement error, which indicates that the training event did not significantly improve their performance. In comparison, the CQP group achieved statistically greater accuracy when placing five out of the six precordial electrodes (refer to Table 2). In addition, Figure 4 depicts the spatial direction of all electrode misplacement errors for both groups. The figure highlights that the standard group suffer from superior misplacement of electrodes V1 and V2 and inferior misplacement of the remaining electrodes.

Figure 5 clearly shows that the participants on average are much more consistent when using the CQP to reapply electrodes onto the same patient model at a later time. Interestingly, the reproducibility of electrode V6 is not as consistent even when using the CQP. However, researchers have reported that the morphology of lead V6 is not significantly affected by the variability of electrode positioning [6].

NASA-TLX scores (Figure 6) revealed that the CQP slightly increased the cognitive workload of the participant, but this was without any statistical significance (CQP Group=16.51%±8.11 vs. standard group=12.22%±8.07,

$p=0.251$). Cognitive workload could also be greater due to the lack of familiarity with the device. Moreover, Figure 6 shows that the CQP achieved a high mean SUS score of 91 ± 7.28 , ranking it within the top 10% of the most human-device friendly interfaces according to a Gaussian distribution of pre-collected SUS scores [24].

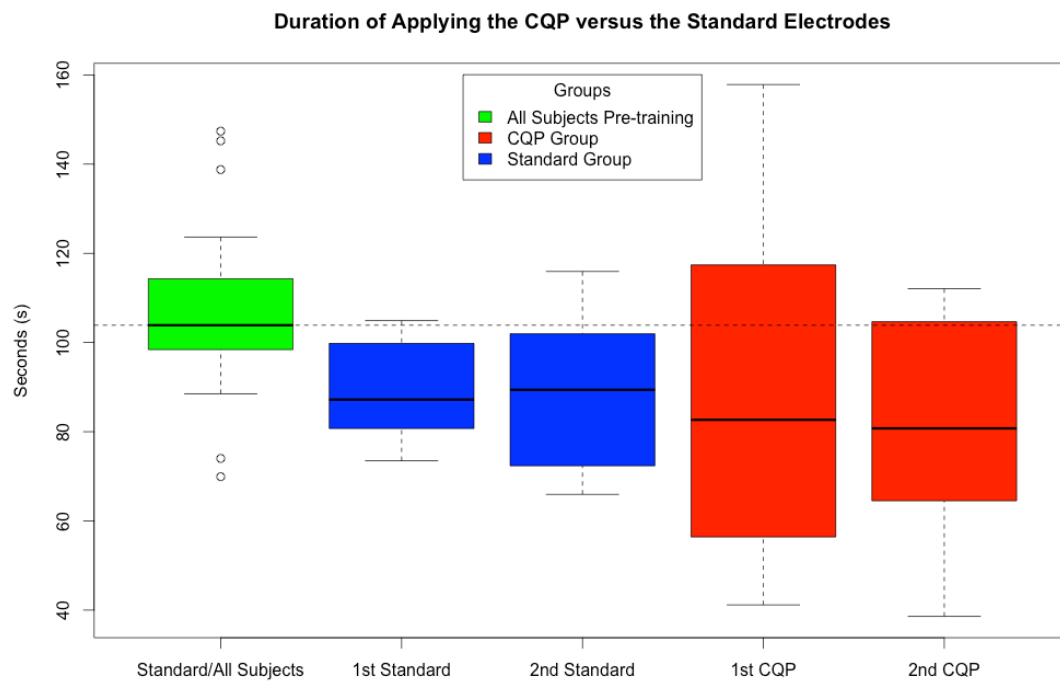


Figure 2. Duration of applying the CQP in comparison to standard electrodes (the group designated as 'Standard/All Subjects' shows the durations achieved by all participants from both groups using the standard single electrodes before the retraining event. The text '1st' and '2nd' refer to Phases 3 and 4 which is the '1st' and '2nd' instances of electrode applications respectively). Box plots represent interquartile ranges (central lines= medians) and the whiskers represent the maximum and minimum values (unless values are greater than 1.5*IQR which are regarded as outliers).

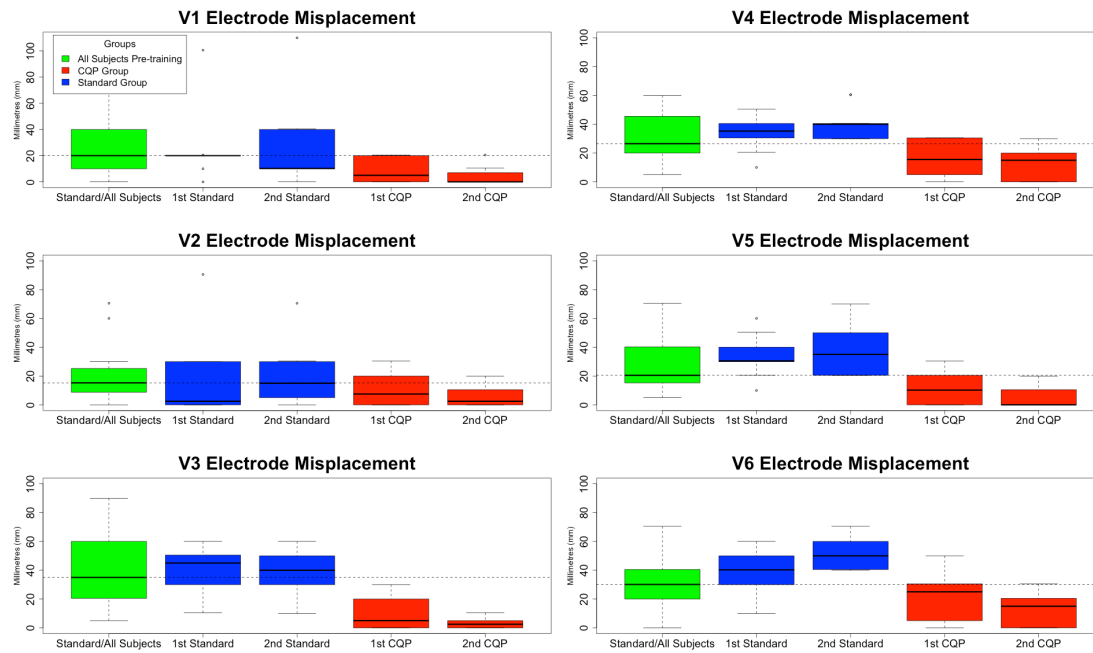


Figure 3. Distance of electrode misplacement when using the CQP and the standard electrode application approach (the dashed line represents a baseline indicating the median electrode misplacement of all participants when applying standard single electrodes before the re-training event in Phase 2). Box plots represent interquartile ranges (central lines=medians) and the whiskers represent the maximum and minimum values (unless values are greater than 1.5*IQR which are regarded as outliers).

Table 2. Shows the mean \pm SD of electrode misplacement in *mm* and the significance testing between the two groups.

	Standard Group (mean \pm SD in mm)	CQP Group (mean \pm SD in mm)	Δ	<i>p</i> -values
V1	25.35 \pm 29.33	6.68 \pm 8.53	18.67	<0.001
V2	18.1 \pm 24.49	8.8 \pm 9.64	9.30	0.122
V3	38.65 \pm 15.57	6.83 \pm 8.99	31.82	<0.001
V4	37.73 \pm 12.14	14.90 \pm 11.76	22.83	<0.001
V5	35.75 \pm 15.61	8.63 \pm 10.70	27.12	<0.001
V6	44.15 \pm 14.32	18.13 \pm 14.37	26.02	<0.001

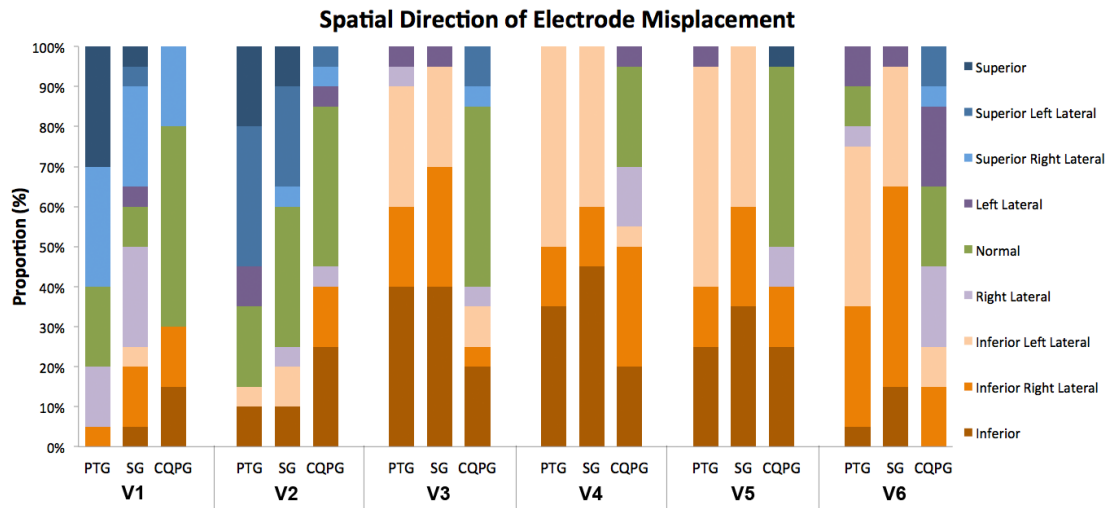


Figure 4. The proportion of electrode misplacement with respect to the spatial direction of the placement error (PTG=Pre-Training Group, SG=Standard Group and CQPG=Cardio-Quick-Patch Group).

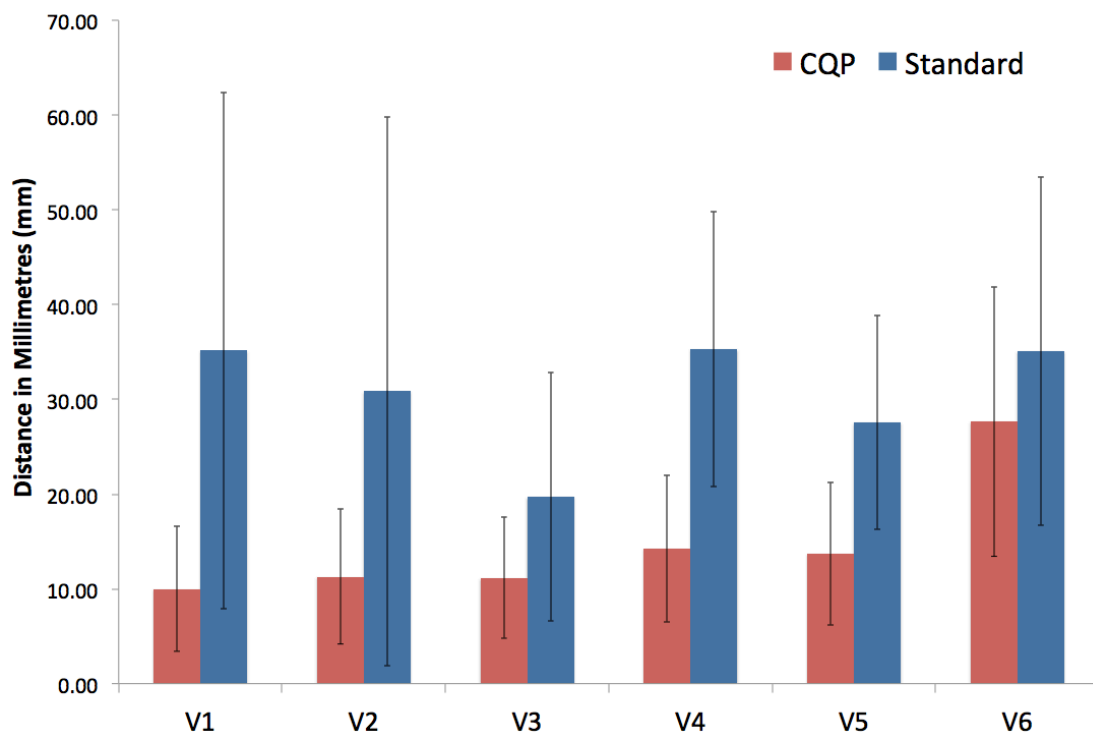


Figure 5. Mean (in mm) reproducibility of standard electrode application versus the application of the CQP (error bars=95% confidence intervals).

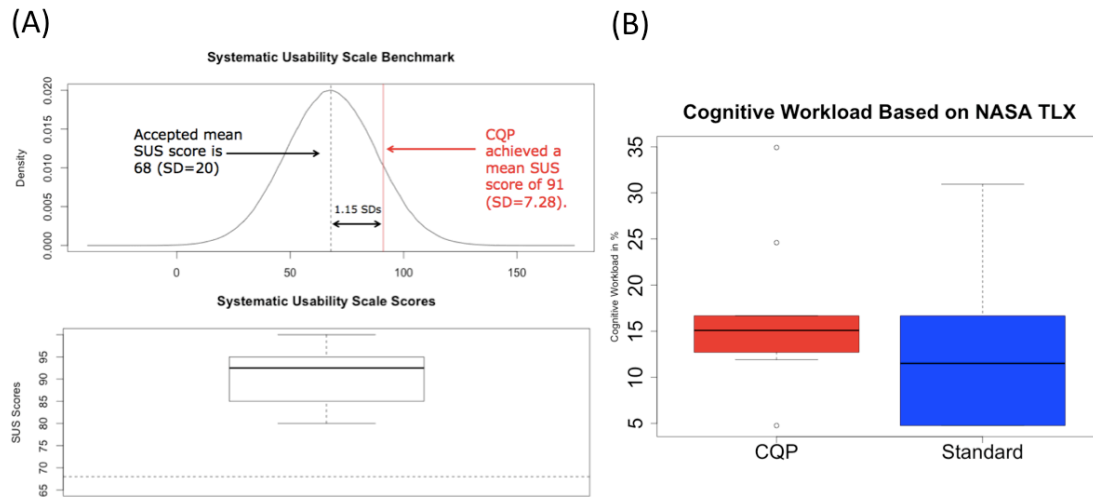


Figure 6. (A) A distribution of SUS scores depicting the mean SUS score attained by the CQP benchmarked against the accepted mean SUS score achieved by other user-machine interfaces. There is also a boxplot of individual SUS scores attained by the CQP (where the dashed line indicates the accepted mean SUS score which is used as the benchmark. (B) Shows a boxplot of NASA TLX scores to measure cognitive workload of the participants when applying standard single electrodes and using the CQP.

Discussion

Implementing the CQP into clinical practice will reduce the number of electrode placement errors. This has the potential to improve clinical efficiency by reducing the need for repeat ECG recordings. More importantly, the CQP in clinical practice could reduce the number of cardiac misdiagnoses. It could also reduce the number of cases where anterior STEMIs are concealed due to electrode misplacement. This would result in more cases where timely cardiac reperfusion therapy is administered. In addition, the CQP solution would also improve the serial comparison of ECGs since physicians often use prior ECG recordings as a benchmark to determine any morphological changes in each of the leads in order to determine the development of any cardiac abnormalities. The CQP could be used in clinical trials to ensure precise electrode positioning is used which is important for analyzing the effect of novel drugs on cardiac function. Whilst these are obvious benefits of the device, one constraint of the

CQP is the fact that it is not designed or optimized for improving the recording of right-sided or posterior leads which can be used in clinical practice to interrogate other areas of the myocardium. The CQP has not been approved for use on pediatric patient. This is due to the fact that these patients require much smaller electrodes in order to fit the very close anatomical positions such as V2 through V4.

Limitations of the study include the fact that there were only 20 ECG technicians recruited, and that electrode application was always applied onto the same male patient model. Future work is required in order to repeat the study using a larger cohort and using a greater number of patient models, including females and individuals with varying torso sizes. In addition, the use of the SUS instrument to measure the usability of the CQP has major limitations since some of the questions in the SUS survey are not applicable to product interfaces such as the CQP. As such, the SUS score is likely to be higher by default. Another limitation involved the fact that participants were incentivized for their participation. However, it is unlikely that an incentive could change a person's competency in ECG acquisition, nevertheless, any bias would be irrelevant since both groups were equally incentivized. As part of our future trials, we plan to undertake a crossover or a within-subject study design in order to remove bias and potential confounders. This would allow us to directly compare how each individual ECG technician performs when using the CQP and when using standard single electrodes.

Conclusion

This work shows that the CQP is a promising solution to the electrode misplacement problem. Using human factors analysis, we showed that the CQP improves the accuracy of electrode placement as well as the reproducibility of electrode application when performed on the same patient (thus reducing intra-practitioner variability). In addition, there is some primitive observational evidence that the CQP reduces the time of electrode application especially since

the CQP group was also disadvantaged as this was the subjects' first attempts in using this device whereas the standard group were already familiar with conventional electrode application. The study also provides evidence that the CQP is a user-friendly device that does not statistically significantly increase the cognitive effort required to use it. Finally, a secondary finding is that short training sessions of proper electrode placement may not necessarily improve the accuracy of placing single standard electrodes in clinical practice, however whilst sustained training could possibly be more effective, we know that traditional medical education has not yet solved this problem.

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